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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,821

09/30/2005

Janus S. Larsen

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BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER

OLSON, ERIC

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

02/29/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/551,821	LARSEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ERIC S. OLSON	1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **Detailed Action**

This office action is a response to applicant's communication submitted December 18, 2007 wherein claims 1-3, 8, and 10 are amended and claims 7 and 11 are cancelled. This application is a national stage application of PCT/EP04/50427, filed April 2, 2004, which claims benefit of provisional application 60/41794, filed April 11, 2003, and claims priority to foreign application DE PA 200300557, filed April 10, 2003.

Claims 1-6 and 8-10 are pending in this application.

Claims 1-6 and 8-10 as amended are examined on the merits herein.

Applicant's amendment, submitted December 18, 2007, with respect to the rejection of instant claim 10 under 35 USC 112, first paragraph, for lacking enablement for treating all possible conditions responsive to modulation of the GABA receptor complex, has been fully considered and found to be persuasive to remove the rejection as claim 10 has been amended to recite certain specific conditions that are enabled by Applicant's disclosure. Therefore the rejection is withdrawn.

Applicant's amendment, submitted December 18, 2007, with respect to the rejection of instant claims 10 and 11 under 35 USC 112, first paragraph, for lacking enablement for a method of preventing the recited disorders, has been fully considered and found to be persuasive to remove the rejection as claim 10 has been amended to no longer be drawn to preventative methods. Therefore the rejection is withdrawn.

Applicant's amendment, submitted December 18, 2007, with respect to the rejection of instant claims 1, 3, 4, 7, and 9-11 under 35 USC 102(b) for being anticipated by Teuber '98, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require an alkoxyalkyl, alkoxyalkenyl, or alkoxyalkynyl group in position R' of the compound, said groups not being taught by Teuber '98. Therefore the rejection is withdrawn.

The following rejections of record in the previous office action are maintained:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Teuber '00. (PCT international publication WO00/78728, reference included with PTO-1449, equivalent to US patent 6649609) Teuber '00. discloses a range of compounds including the compounds of claim 1. (pp. 3-6, wherein R<sup>2</sup> is alkyl, hydroxyalkyl, alkoxyalkyl, or alkyl-N-R<sup>3</sup>R<sup>4</sup>, and R'' is "heterocycle" representing pyrrolidin-1-yl, piperazin-1-yl, imidazolyl-1-yl, or pyridine-4-yl including piperidin-4-yl (see p. 11, lines 15-19) substituted with hydroxyalkyl or alkoxyalkyl) When the heterocycle is piperazine, the compound anticipates claim 2, and when the heterocycle is piperidine the compound anticipates claim 3. These compounds are disclosed as pharmaceutical

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compositions together with at least one pharmaceutically acceptable carrier, excipient, or diluent, and are useful in methods of treating disorders responsive to modulation of the GABA receptor complex. (p. 6, lines 7-21) They are also useful as anesthetics, pre-anesthetics, sedatives, muscle relaxants, and anticonvulsants. (p. 2, lines 30-33)

Therefore the claimed invention is anticipated by Teuber '00.

Response to Argument: Applicant's arguments, submitted December 18, 2007, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the claims have been amended to require a "lower" alkoxyalkyl group in position R'. However, p. 3, lines 19-22 specifically recite alkoxyalkyl as one possible substituent for this position. (referred to in this reference as R'') Furthermore, p. 18, lines 1-8 of Teuber '00 discloses that the preferred embodiment of "alkyl" is C<sub>1-6</sub>, C<sub>1-4</sub>, or C<sub>1-3</sub>, all of which fall within the definition of "alkyl" recited in p. 7, lines 22-28 of the instant specification. Therefore the claims as amended still encompass these embodiments of the invention of Teuber '00 and are anticipated by this reference. For these reasons the rejection is maintained and made **FINAL**.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Teuber '00. (PCT international publication WO00/78728, reference included with PTO-1449, equivalent to US patent 6649609) The disclosure of Teuber '00 is discussed above. Additionally, on pp. 16-17 Teuber '00 discloses a number of specific embodiments having structures similar to those of instant claim 8, for example 2-Hydroxyethyl 1-(3-(4-(2-hydroxyethyl)-1-piperazinyl)-phenyl)- benzimidazole-5-carboxylate. (p. 16, lines 38-39) Teuber '00 does not specifically exemplify the compounds recited in instant claim 8.

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce the compounds of claim 8. One of ordinary skill in the art would have been motivated to produce various embodiments of the general formula of Teuber '00 and to evaluate them for their usefulness in the claimed invention. Because these compounds fall within the limits of the general formula disclosed by Teuber '00, and because they are similar in structure to the specific embodiments disclosed therein, it would have been obvious to produce and evaluate them.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted December 18, 2007, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the claimed invention produces unexpected results over the compounds of Teuber '00, and provides Exhibit I, which illustrates similar binding strengths and significantly increased therapeutic effect on PTZ-induced clonic convulsions when compound 1F of the invention is compared to compound 1cc of Teuber et al. Firstly, in order to be considered as evidence of

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unexpected results, the data relied upon must be either included in the specification as originally filed or entered as an affidavit or declaration under 37 CFR 1.132. Secondly, the results provided by Applicant only serve to disclose increased therapeutic activity of one inventive compound over one prior art compound. Claim 8 as amended includes 17 compounds which differ in positions R and R'. Given that a slight difference in the position R' produces the claimed increased therapeutic efficacy, there is no way of knowing based on the data provided which other compounds of the claimed invention share this increased efficacy. In particular, compounds with alkoxyalkenyl or alkoxyalkynyl substituents, or with alkyl groups other than ethyl or alkyloxy groups other than methoxy, may or may not possess the claimed unexpected activity. This is particularly true because the mechanism by which the unexpected results are produced is unknown, As the binding affinity of the two compounds for their molecular target is similar while the magnitude of their *in vivo* physiological effect is different.

For these reasons the rejection is deemed proper and made **FINAL**.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6, and 9-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, and 10-12 of U.S. Patent No. 6649609. (Cited in PTO-892, herein referred to as '609) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-7 and 9-11 of '609 anticipate the claimed invention. Claims 1 and 7 of '609 disclose a formula that anticipates the instant claims when  $R^2$  of claim 1 of '609 is hydroxyalkyl or alkoxyalkyl, o is 0, Y is  $NR^{11}$ , and  $R^{11}$  is hydroxyalkyl or alkoxyalkyl. When X is N, '609 anticipates instant claim 2 and when X is CH, it anticipates instant claim 3. Claims 10-12 of '609 claim the same compositions and methods as instant claims 9-11. Thus the claimed invention is anticipated by claims 1, 7, and 10-12 of '609.

Response to Argument: Applicant's arguments, submitted December 18, 2007, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the claimed invention produces unexpected superior properties compared to the invention claimed by '609. Firstly, the unexpected properties recited are not sufficient to demonstrate unexpected results over the full scope of the claimed invention as discussed above under 103 rejections. Secondly, the claimed species are anticipated by claim 7 of '609. In



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particular, where  $Y = NR^{11}$ ,  $R^{11} = \text{alkyl-}R^5$ , and  $R^5 = \text{alkoxy}$ . According to column 14, lines 16-26 of '609, the preferred embodiment of "alkyl" is  $C_{1-6}$ ,  $C_{1-4}$ , or  $C_{1-3}$ , all of which fall within the definition of "alkyl" recited in p. 7, lines 22-28 of the instant specification. Therefore this embodiment of the invention claims in '609 is seen to anticipate the claimed invention.

For these reasons the rejection is deemed proper and made **FINAL**.

### Conclusion

No claims are allowed in this application. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/  
Examiner, Art Unit 1623  
2/15/2008

/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623